

Application No.: 10/727,777  
Amdt dated August 31, 2005  
Reply to Office action of June 9, 2005

### **REMARKS/ARGUMENTS**

Claims 1-6, 8-14, 17, 18, 20-27 and 31-39 are pending in the application. By this Amendment, claims 7, 15, 16, 19 and 28-30 have been canceled, claims 1, 6, 20, 21, 22, 24, 25, 27, 31 and 32 are amended, claims 34-39 are new, and the drawings are corrected. The amendments to the claims do not introduce new matter as they are fully supported by the specification, claims and drawings as originally filed. The amendments to the drawings do not introduce new matter as they are fully supported by the specification and the claims as originally filed. Applicants respectfully request reconsideration of claims 1-6, 8-14, 17, 18, 20-27 and 31-39 in view of the above amendments and the following remarks.

Independent claim 1 has been amended to incorporate all of the limitations of dependent claim 19. Claim 25 has been amended to incorporate all of the limitations of dependent claim 30. Thus, Applicants respectfully submit that claims 1 and 25 are now allowable.

Claims 1-24 were objected to based on alleged informalities that it was not clear whether the terms "proximal end" and "distal end" in lines 2-3 of Claim 1 referred to the ends of the tubular member or of the lumen. Claim 1 was amended to correct the informalities. Claims 2-24 were objected to as being dependent on Claim 1. As the informalities of Claim 1 have been corrected, Applicants respectfully submit that the objections to Claims 2-24 are now moot.

Application No.: 10/727,777  
Amdt dated August 31, 2005  
Reply to Office action of June 9, 2005

Claims 6, 7, 22, 24, 27 and 32 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6, 24 and 27 have been amended to overcome the rejection and Claim 7 has been canceled. The Specification has been amended to describe the "snap-on plug" features as depicted in the drawings as originally filed, thereby overcoming the rejection of Claims 22 and 32. Applicants respectfully submit that claims 6, 22, 24, 27 and 32 are now allowable.

Claims 1-3, 5, 6, 8-14, 18, 23, 25-27 and 33 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,606,889 to Arblaster. Applicants respectfully traverse these rejections because Arblaster does not disclose the claimed invention.

To be anticipating, a prior art reference must disclose each and every limitation of the claimed invention. More particularly, "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*" Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Found. v. Genentech Inc., 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991).

As stated above, Claim 1 was amended to incorporate all of the limitations of

Application No.: 10/727,777  
Amdt dated August 31, 2005  
Reply to Office action of June 9, 2005

dependent Claim 19. Canceled Claim 19 recited "[t]he percutaneous drainage catheter of claim 1, further comprising a connector hub 62 at the proximal end including a port 64 and an access lumen plug 66." Arblaster does not disclose the connector hub at the proximal end including a port and an access lumen plug. Claim 1, as currently amended, recites "[a] percutaneous drainage catheter[,] comprising a tubular member 50 having a drainage lumen 52[,] . . . a retention member[,] . . . and a connector hub 62 at the proximal end including a port 64 and an integral access lumen plug 66. . . ." (Emphasis added.) Canceled Claim 19 did not include language that the access lumen plug is integral with the catheter, but support is found for the integral access lumen plug in the drawings as originally filed, where FIGS. 4A and 4B depict the plug 66 as part of the connector hub 62, which in turn is connected to the tubular member 50.

Arblaster does not disclose the catheter having the access lumen plug of canceled Claim 19 at the proximal end as recited in applicants' amended Claim 1. Canceled Claim 19 was rejected under 35 U.S.C. 103(a) as being unpatentable over Arblaster in view of U.S. Patent No. 5,906,575 to Conway et al. The Examiner indicated that Arblaster shows a rubber plug for the inflation lumen, but does not show an access lumen plug. The Examiner further indicated that Conway teaches a disposable device to block the flow of urine, which includes a removable stylet capable of functioning as a plug for a drainage lumen.

Conway does not teach the removable stylet as being integral to the catheter. Furthermore, Conway does not teach the removable stylet as a device being used

Application No.: 10/727,777  
Amdt dated August 31, 2005  
Reply to Office action of June 9, 2005

for blocking the flow of urine or as a device capable of functioning as a plug for a drainage lumen. First of all, since the stylet of Conway is removable (see Conway, col. 4, lines 60-63), it is not integral to the catheter. Next, the stylet of Conway has a body with a diameter that is less than the inside diameter of the shaft of the tubular member to facilitate easy insertion and withdrawal of the stylet and the stylet has the necessary rigidity to facilitate the insertion of the apparatus into the urinary tract. (See Conway, col. 7, lines 23-46.) Having a body diameter less than the inside diameter of the tubular member, the stylet of Conway is not likely to function as a plug for a drainage lumen and Conway did not intend the stylet to function as a plug. Rather, as described in Conway's disclosure, Conway intends the stylet to merely facilitate the insertion of the apparatus 20 into the urinary tract. (See Conway, col. 7, lines 42-46.)

Based on the Conway disclosure, one of ordinary skill in the relevant art would not make the inventive leap to use the removable stylet of Conway as a device to block the flow of urine or contemplate the stylet of Conway as being capable of functioning as a plug for a drainage lumen. Thus, Applicants respectfully submit that amended Claim 1 is now allowable over Arblaster.

Claim 1 was also rejected under 35 U.S.C. 102(b) as being anticipated by Conway. The above-arguments in relation to the rejection of independent Claim 1 under 35 U.S.C. 103(a) apply equally here. Accordingly, Applicants respectfully submit that amended independent Claim 1 is allowable over Arblaster and Conway because neither Arblaster nor Conway discloses, nor suggests, each and every

Application No.: 10/727,777  
Amdt dated August 31, 2005  
Reply to Office action of June 9, 2005

feature of the claimed invention. As amended independent Claim 1 is allowable, dependent claims 2-6, 8-14, 17, 18 and 20-24 are also allowable. Additionally, new dependent claims 34-37 are also allowable.

Independent Claim 25 was rejected under 35 U.S.C. 102(b) as being anticipated by both Arblaster and Conway. Dependent Claim 30 was rejected under 35 U.S.C. 103(a) as being unpatentable over Arblaster in view of Conway, as described for Claims 19 and 20. Independent Claim 25 was amended to incorporate all of the limitations of dependent Claim 30. Canceled Claim 30 recited "[t]he percutaneous drainage catheter of claim 25, further comprising a connector hub 62 at a proximal end of the tubular member 50 including a port 64 and an access lumen plug 66." As stated above, Arblaster does not disclose the connector hub at the proximal end including a port and an access lumen plug. Claim 25, as amended, recites "[a] percutaneous drainage catheter[,] comprising a tubular member 50 having a drainage lumen 52 . . . and a drainage portion[,] . . . a retention member[,] . . . and a connector hub 62 at a proximal end of the tubular member 50 including a port 64 and an integral access lumen plug 66. . . ." (Emphasis added.) Similar to canceled Claim 19, canceled Claim 30 did not include language that the access lumen plug is integral with the catheter, but support is found for the integral access lumen plug in the drawings as originally filed.

The arguments made above in relation to Claims 1 and 19 apply equally here. Additionally, Claim 25 was amended to claim that the retention member 56 is formed "around" the tubular member 50, rather than being formed "proximally to" the tubular

Application No.: 10/727,777  
Amdt dated August 31, 2005  
Reply to Office action of June 9, 2005

member 50, in order to have Claim 25 correspond with the Specification and Drawings. Accordingly, Applicants respectfully submit that amended independent Claim 25 is allowable over Arblaster and Conway because neither Arblaster nor Conway discloses nor suggests each and every feature of the claimed invention. As amended independent Claim 25 is allowable, dependent claims 26, 27 and 31-33, and new dependent claims 36 and 37 are also allowable.

Claim 21 was rejected under 35 U.S.C. 103(a) as being unpatentable over Arblaster in view of Conway and further in view of U.S. Patent No. 4,705,510 to Rosenberg. Applicants' Claim 21 was dependent on Claim 19 and was amended to be dependent on amended Claim 1. As stated above, since Arblaster and Conway fail to teach or suggest a drainage catheter having the integral access lumen plug at the proximal end of the tubular member of the catheter, Applicants respectfully submit that Claim 21 is now dependent on allowable independent Claim 1 and is, therefore, allowable.

Claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over Arblaster in view of Conway and further in view of U.S. Patent Publication No. US 2003/0060807 to Tanghoj et al. Applicants' Claim 22 was dependent on Claim 19 and is currently amended to be dependent on amended Claim 1. As stated above, Arblaster and Conway fail to teach or suggest a drainage catheter having the integral access lumen plug at the proximal end of the tubular member of the catheter.

Tanghoj fails to correct the deficiencies of Arblaster and Conway. Claim 22

Application No.: 10/727,777  
Amdt dated August 31, 2005  
Reply to Office action of June 9, 2005

recites that the access lumen plug operates like a snap-on plug. Applicants' Claim 1 recites that the access lumen plug is integral with the proximal end of the catheter. Tanghoj does not teach a catheter having an access lumen plug that is integral with the proximal end of the catheter. Rather, Tanghoj teaches a urinary catheter housed within a catheter package that includes a "closure" 19 or 69 at the distal end of the catheter package. (See Tanghoj, Figs. 1c and 6a-6c, paragraph 0086 and paragraph 0096.) Please note that Tanghoj refers to the end of the catheter that is adapted for insertion into the urethra of an individual as the "proximal end" of the catheter (see Tanghoj, paragraph 0079), whereas Applicants refer to the portion of the catheter where the retention member is located and that is placed into a body cavity as the "distal portion" of the catheter (see Application page 8, lines 9-18 and Figs. 4A and 4B). More particularly, what Tanghoj refers to as the proximal end of the catheter, Applicants would refer to as the distal end, and vice versa.

The "closure" for the catheter package in Tanghoj does not close the access lumen of the catheter; instead, the "closure for the package in Tanghoj closes the distal end of the package in which the catheter is housed following a catheterization procedure, whereas the plug in the Application plugs the proximal end of the tubular member while the distal end of the catheter is still in place within an individual or other animal. The "closure" in Tanghoj, by design, cannot be closed while the distal end of the catheter is in place within an individual. Based on the Tanghoj disclosure, one of ordinary skill in the relevant art would not make the inventive leap to add an integral plug to the proximal end of a drainage catheter for plugging the access

Application No.: 10/727,777  
Amdt dated August 31, 2005  
Reply to Office action of June 9, 2005

lumen of the catheter or contemplate the "closure" of Tanghoj as being capable of plugging the proximal end of the access lumen of the catheter. Accordingly, Applicants respectfully submit that Claim 22 is now allowable.

Claim 31 was rejected under 35 U.S.C. 103(a) as being unpatentable over Arblaster in view of Conway as described for Claim 20. Based on the arguments above in relation to Claim 20, Applicants respectfully submit that Claim 31 is now allowable.

Claim 32 was rejected under 35 U.S.C. 103(a) as being unpatentable over Arblaster in view of Conway as described for Claim 19, and further in view of Tanghoj as described for Claim 22. Based on the arguments above in relation to Claim 22, Applicants respectfully submit that Claim 32 is now allowable.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

APPLIED MEDICAL RESOURCES

BY



David G. Majdali  
Reg. No. 53,257  
Tel: (949) 713-8233

Attachments



Application No.: 10/727,777  
Amdt dated August 31, 2005  
Reply to Office action of June 9, 2005

**Amendments to the Drawings:**

The attached sheets of drawings include changes to FIGS. 1, 2, 3A and 3B. In particular, in FIGS. 1, 2, 3A and 3B, the phrase –Prior Art— is added below the figure number references. Additionally, reference numeral “20” is removed from each of FIGS. 3A and 3B.

Attachment: Replacement Sheets